

HiScale 10/40 empty column and prepacked Validation columns

Chromatography columns for robust process validation

Including viral clearance studies

Formats suitable for scale-down studies

Process validation is typically conducted using a scale-down column format. Important characteristics for scale-down chromatography columns include (Fig 1):

- Narrow inner diameter to limit the use of sample and resin, for example 10 mm
- Bed heights commonly used in large-scale processes

We have developed our scale-down columns in close collaboration with biomanufacturers working in process validation.

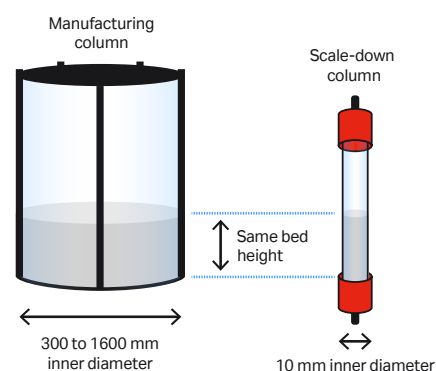


Fig 1. Schematic description of scale-down chromatography model.

Two options: empty or prepacked columns

Add flexibility

Two options for scale-down columns

Save time

Empty HiScale™ 10/40 column



- Easy to pack, to obtain high-quality packed bed
- Max operating pressure: 20 bar (2 Mpa, 290 psi)
- Inner diameter: 10 mm
- Bed height: flexible, from 10 to 40 cm
- Bed volume: 8–31 mL

Prepacked Validation columns

(prepacked Tricorn™ column with a choice of BioProcess™ resins)



- High quality packing — packed by our experts
- Certificate — supplied with each column
- Inner diameter: 10 mm
- Bed height: fixed, 20 cm
- Bed volume: 15.7 mL

Empty HiScale 10/40 column

Easy to pack with flexibility to choose resin and bed height

- Axial compression capabilities, a nonrotating plunger mechanism, and column measurement scale
- Flexibility to adjust resin bed height during column packing (Fig 2)

Prepacked validation columns

High-quality packing for excellent reproducibility and time savings

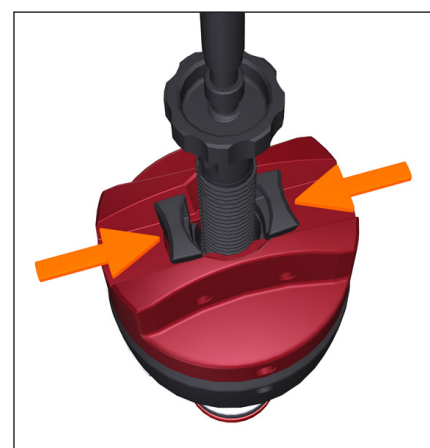
- Packed by our experts
- Results of Analysis certificate available for each individual column — includes column performance testing such as asymmetry and efficiency (Fig 3)



Fig 3. Efficiency analysis for 20 different MabSelect SuRe™ Validation columns showing high quality packing with theoretical plate numbers per meter above the limit (3000) and consistency between the packed columns.



Adjustment of the end cap on HiScale columns enables controlled axial compression of the gel bed.



QuickLock mechanism on the column end caps enables simplified adapter movement.

Fig 2. HiScale columns are easy to pack (picture showing HiScale 50).

Pros and cons of empty vs prepacked columns

	Empty columns	Prepacked columns
+ Advantages	<ul style="list-style-type: none"> • Increase bed height flexibility • Know the compression factor • Reduce cost 	<ul style="list-style-type: none"> • Save time • Improve reproducibility • Eliminate need for packing expertise • Receive quality certificate with each column
- Disadvantages	<ul style="list-style-type: none"> • Need in-house column packing expertise • More time-consuming than prepacked columns 	<ul style="list-style-type: none"> • Less control of packing: <ul style="list-style-type: none"> - need to trust the column packing supplier - compression factor unknown

Ordering information

Product name	Product code	Resin bed height	Inner diameter	Max operating pressure of the column hardware	Bed volume
HiScale 10/40	29360550 ¹	10–40 cm	10 mm	20 bar (2 MPa, 290 psi)	8–31 mL
MabSelect™ Prisma Validation column	29321909				
MabSelect SuRe Validation column	29315187				
MabSelect SuRe LX Validation column	29340185				
Capto™ S ImpAct Validation column	29321910	20 cm	10 mm	50 bar (5 MPa, 725 psi)	15.7 mL
Capto SP ImpRes Validation column	29315186				
Capto Q Validation column	29363635				
Capto adhere Validation column	29315195				

¹ HiScale 10/40 will be available during first half of 2019.

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